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OFFICIAL WEBSITE NOTICE Posting Date: June 27th, 2013

RECOMMENDATIONS OF DRUG USE REVIEW / PHARMACY AND THERAPTUETICS COMMITTEE

The Oregon Drug Use Review / Pharmacy and Therapeutics Committee met in Wilsonville, Oregon on Thursday, May 30th, 2013. The committee considered in order of priority: the safety and efficacy of the drugs being considered, the ability of Oregonians to access effective prescription drugs that are appropriate for their clinical conditions and finally, substantial differences in costs of drugs within the same therapeutic class. Based upon the clinical information presented by staff ⁱand all public comment offered, ⁱⁱ while considering the impact on special populations, the Committee makes the following recommendations for the Oregon Prescriber-Managed Prescription Drug Plan (PMPDP) or for any other preferred drug list established by the Oregon Health Authority:

Drug Use Review Recommendations:

HCMB Process

The Committee recommended establishing a subcommittee to act as an advisory committee that includes representation from the P&T committee, as well as the HERC. Depending on the topic, consider professional or lay experts, a general expert in such areas as statistics, and patient advocate or patient advocate groups.

Makena (17-HP) NDE

The Committee recommended requiring prior authorization for 17-HP to limit use to women with a singleton gestation and a prior spontaneous preterm singleton birth between 16 weeks, 0 days and 20 weeks, 6 days of gestation, regardless of transvaginal ultrasound cervical length, to reduce the risk of recurrent spontaneous preterm birth. Treatment should be continued through 36 weeks of gestation or delivery, whichever occurs first.

The Committee found insufficient data to support use of the compounded product and due to the additional inherent compounding risks, recommended preferring the branded product and opening Makena to POS billing.

Fycompa NDE

The Committee found a lack of comparative effectiveness data that perampanel is more effective or safer than other antiepileptic agents for managing partial-onset seizures and recommended designating perampanel a second line non-preferred oral anticonvulsant, to ensure appropriate use as adjunct treatment when previous treatment with other AEDs has not provided adequate response or has not been tolerated.

Teriflunomide NDE

The Committee recommended designating teriflunomide non-preferred and to prior authorize to limit use to confirmed patients with documentation of prior failed use of an interferon for MS or glatiramer acetate and appropriate laboratory monitoring. The Committee also recommended requiring proof of contraception for women of childbearing age to criteria

Acthar Gel

The Committee recommended requiring prior authorization for repository corticotropin injection, allowing coverage for the treatment of infantile spasms in patients less than 2 years of age.

The Committee also recommended requiring manual review of claims for patients >2 years of age and restrict other use to those who cannot tolerate appropriate glucocorticoid therapy.

CF Vitamins

The Committee found that due to the consensus among CF practitioners that routine supplementation with fat-soluble vitamin preparations is necessary in patients with CF, they recommended comparing and adding appropriate formulations (e.g. VitamaxTM or AquADEKTM) to the list of supplements that are included in the rebate exception policy.

The Committee also directed staff to further evaluate the vitamin and supplement policy for appropriate coverage.

The Committee made a broader recommendation to encourage CCO's to evaluate their CF vitamin utilization and adopt similar coverage guidelines. Information will be shared through the medical and/or pharmacy director meetings.

Lomitapide and Mipomersen NDE

The Committee recommended designating lomitapide and mipomersen as non-preferred and to require manual review and prior authorization to limit use to confirmed adult HoFH patients that have failed or are unable to tolerate maximum lipid-lowering therapy and LDL-C apheresis. The Committee recommended approval for genetically confirmed HoFH only, who have a medical contraindication to lipid lowering therapy and LDL apheresis and require it be prescribed in consultation with a specialist.

The Committee directed staff to reach out to a specialist to gather information on the reliability of genetic testing and bring the information back to the committee with more specific criteria that defines apheresis failure.

Practitioner-Managed Prescription Drug Plan (PMPDP) Recommendations:

Cough and Cold Product Scan

The Committee recommended that no further research was needed at this time and to evaluate comparative costs in executive session.

After comparative cost consideration in executive session the Committee recommended making this a PDL class and to designate only the lower cost GSNs as preferred: guaifenesin liquid 100mg/5ml, guaifenesin/dextromethorphan syrup, guaifenesin/codeine phosphate liquid, pseudoephedrine HCL tablets 30mg and 60mg. The Committee also recommended considering the addition of benzoate capsules as a preferred alternative to Mucinex tablets.

Topical Antibiotics Scan

The Committee recommended that no further research was needed at this time and to evaluate comparative costs in executive session.

After comparative cost consideration in executive session, the Committee recommended to designate double-antibiotic ointment as preferred and designate Centany AT Kits non-preferred.

Oral Immunosuppressants Scan

The Committee recommended that no further research was needed at this time and to evaluate comparative costs in executive session.

After comparative cost consideration in executive session the Committee recommended designating Myfortic and Sandimmune solution as preferred to be consistent with previous recommendations.

The Committee has made these recommendations to the Oregon Health Authority for approval by the Director of the Oregon Health Authority.

APPROVAL BY THE DIRECTOR OF THE OREGON HEATLH AUTHORITY

The recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee are approved. Recommendations with respect to the inclusion of a drug on the Practitioner-Managed Prescription Drug Plan will be put into place no earlier than 60 days from the date this notice is posted on the web site.

Bruce Goldberg, M.D.

Director, Oregon Health Authority

Approval date

A request for reconsideration of this decision to adopt the recommendations of the Drug Use Review / Pharmacy and Therapeutics Committee must be filed with and received by the Director no later than 30 calendar days from the date of this notice. 2011 OR law, CH 730 (HB2100) Section

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